

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/412,297	TING, KANG	
	<b>Examiner</b>	<b>Art Unit</b>	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--  
 All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to October 20, 2005.
2. ☒ The allowed claim(s) is/are 1-2, 8-12, 51 and 54 are allowed (renumbered 1-9, respectively).
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

- |   |   |
|---|---|
| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08)<br/>           Paper No./Mail Date <u>3/26/02, 8/4/04, 1/13/04 + 11/16/04</u></li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</li> <li>6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br/>           Paper No./Mail Date <u>10/11/05, 12/9/05 + 12/14/05</u></li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____</li> </ol> |
|---|---|

**ALLOWANCE**

1. This Office Action is responsive to Applicant's amendment and remarks filed October 20, 2005. Claim 53 has been cancelled. Claims 3-7 and 13-50 have been cancelled by Examiner's amendment. All rejections of record are withdrawn in view of Applicant's amendment and remarks. The restriction requirement mailed December 5, 2000 is withdrawn. Claims 1-2, 8-12, 51 and 54 (renumbered 1-9, respectively) are allowed.

***Examiner's Amendment***

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Zhaoyang Le on December 9, 2005 to cancel claim 52 by Examiner's amendment. Authorization for this examiner's amendment was given in a telephone interview with Mr. Zhaoyang on December 14, 2005 to cancel non-elected claims by Examiner's amendment.

In the claims:

A. Claims 3-7, 14-50 have been cancelled.

***Examiner's Reasons for Allowance***

3. The following is an examiner's statement of reasons for allowance. The prior art cited neither teaches nor suggests a method for screening for an agent that modulates bone mineralization said method comprising: contacting an osteogenic cell expressing a Nell-1 gene with a test agent and detecting an expression level of said NELL-1 gene in the contacted cell, where a difference in the expression level of NELL-1 is an osteogenic cell that is not contacted indicates that said test agent is an agent that modulates bone mineralization, wherein the osteogenic cell is selected from the group consisting of an osteoblast, a mesenchymal, a fibroblast cell, a dura cell, a chondrocyte, a MC3T3 cell and a chondroblast.

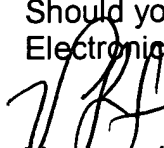
Art Unit: 1645

4. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Vanessa L. Ford  
Biotechnology Patent Examiner  
December 19, 2005



**LYNETTE R. F. SMITH**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**

***CLEAN COPY OF CLAIMS***

1. (previously presented) A method for screening for an agent that modulates bone mineralization, said method comprising:

contacting an osteogenic cell expressing a NELL- 1 gene with a test agent; and  
detecting an expression level of said NELL-I gene in the contacted cell, where a difference in the expression level of NELL-I in an osteogenic cell that is not contacted indicates that said test agent is an agent that modulates bone mineralization, wherein the osteogenic cell is selected from the group consisting of an osteoblast, a mesenchymal cell, a fibroblast cell, a dura cell, a chondrocyte, a MC3T3 cell and a chondroblast.

2. (previously presented) The method of claim 1, further comprising recording test agents that modulate expressions of the NELL-I nucleic acid or NELL- 1 protein in a database of test agents modulating NELL-I activity or in a database of test agents modulating bone mineralization.

Claims 3-7 have been cancelled.

8. (original) The method of claim 1, wherein in said level of NELL-1 is detected by determining the expression level of a NELL- 1 protein in said biological sample.

9. (original) The method of claim 8, wherein said detecting is via a method selected from the group consisting of capillary electrophoresis, a Western blot, mass spectroscopy, ELISA, immunochromatography, and immunohistochemistry.

10. (original) The method of claim 1, wherein said cell is cultured *ex vivo*.

11 (original) The method of claim 1, wherein said test agent is not an antibody.

12. (original) The method of claim 1, wherein said test agent is not a protein.

Claims 13-50 have been cancelled.

51. (previously presented) The method of claim 1, wherein the osteogenic cell is a cell in a fetal calvarial cell culture.

Claims 52-53 have been cancelled.

Art Unit: 1645

54. (previously presented) A method for screening for an agent that modulates bone mineralization, said method comprising:  
contacting an osteogenic cell expressing a NELL-1 gene with a test agent; and detecting an expression level of said NELL-1 gene in the contacted cell, where a difference in the expression level of NELL-1 in an osteogenic cell that is not contacted indicates that said test agent is an agent that modulates bone mineralization.